

1. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-14, 16-18, and 20-30 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437), further in view of Krzysik (U.S. Publication No. 2004/0228811).

Claim 1 is directed to a tissue product comprising a tissue paper and a moisturizing and lubricating composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent, from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent, and an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof. No more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Klofta, et al. disclose an anhydrous lotion composition for killing viruses and bacteria in addition to imparting a soft,

lubricious, lotion-like feel when applied to tissue paper. The lotion composition comprises at least one antimicrobial selected from an antiviral, antibacterial, and mixtures thereof; at least one hydrophilic solvent; at least one skin conditioning agent; and at least one hydrophilic surfactant. When used in the lotion formulation, the antiviral is present in the lotion composition in an amount of from about 1% (by weight) to about 60% (by weight) and the antibacterial is present in an amount of from about 0.1% (by weight) to about 6% (by weight). Hydrophilic solvents can include glycol type solvents such as polyethylene glycols, glycerin, ethylene glycol, propylene glycol, polypropylene glycol, ethanol, isopropanol, hexylene glycol, and mixtures thereof and are present in the lotion composition in an amount of from about 5% (by weight) to about 60% (by weight).¹ Hydrophilic surfactants such as ethoxylated alcohols are present in the lotion formulation in an amount of from about 0.1% (by weight) to about 60% (by weight). Skin conditioning agents include petroleum-based agents such as mineral oil and petrolatum; fatty acid ester type agents, fatty alcohol type agents, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures thereof and are present in the lotion composition in an amount of from about 0.1% (by weight) to about 60% (by weight).² Typically, the skin conditioning agents have either a plastic or fluid consistency at 20°C (i.e., ambient temperatures).³ As the skin conditioning agents have a plastic or fluid consistency at

¹ U.S. 6,238,682 at column 17, lines 41-42.

² *Id.* at column 19, lines 23-26.

³ *Id.* at column 17, lines 50-52.

20°C, they tend to flow or migrate on the surface of the tissue product. The lotion composition can further optionally include an immobilizing agent such as C₁₂-C₂₂ fatty alcohols and C₁₂-C₂₂ fatty acids in amounts of from about 5% (by weight lotion formulation) to about 60% (by weight lotion formulation).⁴

Significantly, Klofta, et al. fail to disclose that their lotion formulation includes from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent as required in claim 1. Further, Klofta, et al. fail to disclose that their lotion formulation includes an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof as required in claim 1.

Recognizing that Klofta, et al. fail to make such a disclosure, the Office cites Krzysik, et al. ('437) and Krzysik ('811) for combination with the Klofta, et al. reference. Specifically, the Office states that it would have been obvious to a person having ordinary skill in the art to combine the cited references as there would be an improved beneficial effect of a soft and lubricious feel and a better maintained skin barrier function, and further, deterioration of the tissue product carrying the lotion composition can be prevented.

The Krzysik ('811) reference is not a proper reference under 103(c). Specifically, Applicants respectfully assert that

⁴ Id. at column 22, lines 51-55.

as the '811 reference has a publication date of November 18, 2004, and the instant application was filed September 11, 2003, the '811 reference is prior art only under 35 U.S.C. §102(e); that is, under its filing date of May 13, 2003.⁵ As stated in 35 U.S.C. §103(c), "subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person." This case is such a case. Specifically, the '811 reference was subject to an assignment to Kimberly-Clark Worldwide, Inc. at the time of the instant application, as shown in the Assignment of the '811 Reference, provided as Exhibit A. Furthermore, the instant application is also subject to an assignment to Kimberly-Clark Worldwide, Inc., as shown in the Assignment provided as Exhibit B. As such, '811 is not properly cited as prior art under 35 U.S.C. §103(a).

Krzysik, et al. ('437) disclose a skin health enhancing soft wet wipe comprising an oil-in-water emulsion composition. The oil-in-water composition comprises a natural fat or oil, sterol or sterol derivative, humectant, emulsifying surfactant, and water. Specifically, in one exemplary embodiment, the oil-in-water composition comprises from about 0.1 to about 30 weight

⁵ 35 U.S.C. 102(e) states that an invention is patentable unless the invention was described in an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent.

percent of natural fats or oils, from about 0.1 to about 10 weight percent of a sterol or sterol derivative, from about 0.1 to about 99.5 weight percent of an humectant, and from about 0.5 to about 20 weight percent of an emulsifying surfactant having an HLB range of about 7 to about 18, from about 45 to about 99.5 weight percent of water and the pH of the emulsion adjusted to a pH of about 4 to about 7.⁶

Significantly, nowhere in '437 is it taught or suggested that the oil-in-water composition contains an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." The Court in *KSR International* further identified a number of rationales to support a

⁶ U.S. 6,440,437 at column 3, lines 21-29.

conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicants' invention and there is no apparent reason for one skilled in the art to modify and/or combine the references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, as noted above, neither the *Klofta*, et al. reference nor the '437 reference, considered alone or in

combination, teach or suggest including an antioxidant in their lotion, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof. Specifically, in addition to the emollient, humectant, immobilizing agent, compatibilizing agent, and skin barrier enhancing agent, the composition of claim 1 includes an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof to minimize or eliminate the development of an offensive odor. As such, this is a significant aspect of Applicants' invention. As the cited references fail to make such a disclosure, the cited references fail to teach or suggest each and every limitation of Applicants' claim 1 as required under MPEP §2143.

Furthermore, even if the cited references did show each element of Applicants' claim 1 (which they do not as Applicants' have explained above), the common sense of one ordinarily skilled in the art would not have provided a reason to combine the Klofta, et al. reference and the '437 reference to arrive at Applicant's composition of claim 1.

As noted in M.P.E.P. §2142, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests a reason for the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). While this test is not a rigid formula, it does provide helpful insight as it can be important to identify a reason that would have prompted a person of ordinary skill in the art to modify the elements as the new invention does. A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the formulations of the Klofta, et al. and the '437 references would not have been made.⁷

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled

⁷ M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. *Grain Processing Corp. v. American-Maize-Products, Co.*, 840 F.2d 902, 904 (Fed. Cir. 1988).

in the art, to combine the Klofta, et al. and '437 references to arrive at Applicants' claim 1. Specifically, a close reading of the '437 reference actually teaches away from the combination of the Klofta, et al. and '437 references. As recognized by the Federal Circuit in *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994),⁸ a reference teaches away "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.".

Specifically, as disclosed in Klofta, et al., it is desirable for the lotion compositions to be **anhydrous** lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.⁹ Moreover, Klofta, et al. explain that the "anhydrous nature of these lotions allows for more efficient dry transfer of the lotion to the skin. Intentional addition of water to the lotion would be **detrimental** to physical properties of the paper such as tensile and caliper. Water aids in the migration of the lotion throughout the web. This leads to fiber debonding and less lotion concentrated at the surface of the paper. This leads to both tensile and caliper losses; thus, it is beneficial to maintain an anhydrous lotion state as described herein."¹⁰ As noted above, however,

⁸ Further upheld in the Board of Patent Appeals case *Ex Parte Osborn and Comstock*, Appeal No. 2007-1572.

⁹ U.S. 6,238,682 at column 10, lines 51-57.

¹⁰ *Id.* at column 10, lines 57-65.

the '437 composition comprises from about 45% to about 99.5% by weight water. The water contained in the '437 composition may be a mixture of water and alcohol. The amount of alcohol in the water is up to about 70 weight percent of the water and alcohol solution.¹¹ Even if alcohol is present in 70 weight percent of the water and alcohol solution, however, the compositions of '437 comprise at least about 13.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the '437 reference, which are desirably incorporated into compositions having at least 13.5% by weight water with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water, and most preferably, less than 0.1% (by weight) water. As such, there is no apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

Claims 2-14, 16-18 and 20-30 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

2. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1 and 23-24 under 35 U.S.C. 103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437), further in view of Krzysik

¹¹ U.S. 6,440,437 at column 3, lines 61-67.

(U.S. Publication No. 2004/0228811), and further in view of Bowser, et al. (U.S. Patent No. 5,342,976).

Claim 1 is discussed above.

Klofta, et al., '437, and '811 are discussed above. Specifically, '811 is not proper as a reference under 35 U.S.C. 103(a). Furthermore, as discussed above, Klofta, et al. and '437 each fail to disclose an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthrocyanidins, and mixtures thereof, and, as noted by the Office, the Klofta, et al. and '437 references fail to teach or suggest a ceramide and glucosylceramide as taught in claims 23 and 24. Furthermore, as noted above, a close reading of the cited references would teach away from a combination thereof.

Recognizing that Klofta, et al. and '437 fail to disclose each and every element of Applicants' claimed invention, the Office cites Bowser, et al. for combination with the Klofta, et al. and the '437 references. Specifically, the Office states that it would have been obvious to a person having ordinary skill in the art to add a ceramide, such as glucosylceramide, as disclosed in Bowser, to a tissue product as there would be a beneficial effect of enhancing skin barrier function. The Bowser, et al. reference, however, fails to overcome the above shortcomings of the Klofta, et al. and the '437 references.

Bowser, et al. disclose a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain ω -hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the skin in an appropriate dilution. One suitable vehicle is water. In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

As noted above, a *prima facie* case of obviousness requires a clear articulation of the reasons why the claimed invention would have been obvious. Initially, as with the Klofta, et al. and the '437 references, the Bowser, et al. reference, fails to teach or suggest including an antioxidant in their lotion, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof. As such, the cited references, alone or in combination, fail to disclose each and every element as required for a *prima facie* case of obviousness.

Furthermore, even if the cited references did show each element of Applicants' claim 1 (which they do not as Applicants' have explained above), neither the references themselves nor the common sense of one ordinarily skilled in the art would have provided a reason to combine the Klofta, et al. reference with the '437 reference and the Bowser, et al. reference to arrive at Applicant's composition of claim 1.

As noted above, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter.

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al., '437, and Bowser, et al. references to arrive at Applicants' claim 1. Specifically, similar to the '437 reference discussed above, a close reading of the Bowser, et al. reference actually teaches away from the combination of the Klofta, et al., '437, and Bowser, et al. references.

Specifically, as noted above, it is desirable for the lotion compositions of Klofta, et al. to be anhydrous lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.¹² Further, as noted above,

¹² U.S. 6,238,682 at column 10, lines 51-57.

Klofta, et al. explain that the intentional addition of water to the anhydrous lotion would be detrimental to physical properties of the paper such as tensile and caliper. As noted above, however, the Bowser, et al. composition can comprise from about 15% to 99.9999% by weight water and, preferably from 50% to 99.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having at least 15% by weight water and, more preferably at least 50% by weight water, with the anhydrous lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.
lotion.

Claims 23-24 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

3. Double Patenting Rejections

Claims 1-14, 16-18, and 20-30 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-61 of copending Application No. 10/659,969.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,969 has not yet issued as a patent.

27839-00139
(K-C 19,378C)
PATENT

Applicants will address the merits of this rejection, as appropriate, if the listed application issues as a patent before the application at hand.

27839-00139
(K-C 19,378C)
PATENT

CONCLUSION

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-14, 16-18, and 20-30 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

/Christopher M. Goff/

Christopher M. Goff, Reg. No. 41,785
ARMSTRONG TEASDALE LLP
One Metropolitan Square, 26th Floor
St. Louis, Missouri 63102
314-621-5070

CMG/JMB
By EFS